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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,245

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Jaime Romero

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,245	Applicant(s) ROMERO, JAIME	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35, 38, 39, 42, 43, 46, 48-67, 70 and 71 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 26, 30, 46, 49, 50 and 52-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-25, 27-29, 32-35, 38, 39, 42, 43, 48, 51, 70, and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged remarks, and terminal disclaimer, filed on 6 February 2009. New claims 70 and 71 in the amendment filed on 20 August 2008 are acknowledged. In the remarks filed on 6 February 2009, applicant indicates the following claims as pending: 23-25, 27-29, 31-45, 47, 51, and 68-71. However, in the last claim set filed (the amendment filed on 20 August 2008), claims 31, 36, 37, 40, 41, 44, 45, 47, 68, and 69 were cancelled. Clarification is requested as to which claims applicant deems currently pending.

The obviousness-type double patenting rejection is hereby withdrawn in view of the terminal disclaimer.

* * * * *

Terminal Disclaimer

The terminal disclaimer filed on 6 February 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on application number 10/910,787 has been reviewed and is accepted. The terminal disclaimer has been recorded.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-25, 27-29, 32-35, 38, 39, 42, 43, 48, 51, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner (U.S. Patent No. 6,210,710) in view of Miller (U.S. Application No. 20050008690), further in view of Cristofori et al. (U.S. Patent No. 5,252,339).

Skinner teaches a timed (sustained) release nutritional supplement (0-99%) (see col. 2, lines 8-22). The disclosed composition is comprised of:

- the stabilizing agent (ascorbic acid) (0-99% - see col. 2, line 49) of instant claims 23-25 (see col. 3, line 58);
- the saccharide (lactose) (0-94% - see col. 4, line 51)) of instant claims 23-25 and 32-35 (see col. 4, line 49);
- the lubricant (magnesium stearate) (0.25-3% - see col. 4, line 61) of instant claims 23-25 (see col. 4, line 59);
- the agglutinative (hydroxyethylcellulose) of instant claims 23-25 (see col. 2, line 66); and
- the core and coating of instant claim 28 (see col. 5, lines 9-26);

Skinner explains that the disclosed composition is beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets (see col. 1, lines 48-56).

While Skinner does not explicitly teach all the instant claimed percentages or the particle size, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages or particle size through routine

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or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges or particle size. Skinner teaches overlapping concentration ranges of stabilizing agent, saccharide, and lubricant (see above).

Skinner teaches that release profiles may be adjusted as desired (see col. 5, lines 15-26). Thus, the release profile of instant claims 23, 51, 70, and 71 may be determined by a person of ordinary skill in the art based on routine experimentation.

Skinner does not disclose a capsule, silicon dioxide, talc, HPMC, Shellac, chondroitin, or glucosamine sulfate.

Miller teaches a capsule formulation (see abstract) comprising:

- talc (see paragraph 0090);
- HPMC (see paragraph 0060);
- Shellac (see example 13);
- chondroitin (90%) (see paragraph 0377 and example 1); and
- glucosamine sulfate (95%) (see paragraph 0377 and example 1).

Miller teaches that the capsule shell may be comprised of hard gelatin (see paragraphs 0009 and 0021), reading on instant claim 70; and a soft gelatin capsule (see paragraphs 0011 and 0021), reading on instant claim 71. The active agent may be in the form of a granulation (see paragraph 0064).

Skinner does not disclose the diethylphthalate of instant claim 45. However, use of diethylphthalate as a plasticizer is well known in the art, as shown by Cristofori (see col. 5, line 2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose water-soluble nutritional supplement in a timed release coated core formulation comprising a saccharide, an excipient, a lubricant, talc, HPMC, shellac, chondroitin, glucosamine, and diethylphthalate, as taught by Skinner in view of Miller, further in view of Cristofori. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides flexibility in release profiles that are stable and economical for compressed tablets, as explained by Skinner.

* * * * *

Response to Arguments

Applicant's arguments regarding the 35 USC 103 rejection filed on 6 February 2009 have been fully considered but they are not persuasive.

1. Applicant argues that Skinner teaches compressed tablets while the instant application claims layered pellets. See remarks, page 5.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Skinner was invoked for the teaching coated core particles (see col. 5, lines 11-17). Miller teaches hard or soft gelatin capsules (see above).

2. Applicant argues that all of the examples in Skinner use single layer compressed tablets. See remarks, page 6.

Examiner respectfully submits that the rejection was based on obviousness as opposed to anticipation. Skinner explicitly envisions coated core particles at col. 5, lines 11-17.

3. Applicant argues that Skinner does not teach glucosamine or chondroitin pellet formulations. See remarks, page 6.

Examiner respectfully submits that Miller was invoked for a teaching of capsules comprising glucosamine or chondroitin granulates.

4. Applicant argues that Miller does not disclose coated pellets. See remarks, page 7.

Examiner respectfully submits that Skinner was invoked for the teaching of coated particulates (pellets) comprising a therapeutic agent.

5. Applicant argues that there is no disclosure in Miller as to the use of shellac as a controlled release pellet coating. See remarks, page 8.

It is noted that the feature upon which applicant relies (i.e., use of shellac as a controlled release pellet coating) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Applicant argues that the combined disclosures of the prior art cited have all the ingredients listed but do not teach how to formulate the pellets. See remarks, page 9.

Examiner respectfully submits that the currently pending claims are product claims, not process claims. As such, a method of formulating the claimed pellets is not relevant to the patentability of the pellets being claimed.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615